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| 09/690,197      | 10/16/2000  | Douglas A. Collins   | COP1001             | 2254             |

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EXAMINER

LUKTON, DAVID

ART UNIT

PAPER NUMBER

1653

21

DATE MAILED: 02/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
**09/690,197**

Applicant(s)  
**Collins**

Examiner  
**David Lukton**

Art Unit  
**1653**



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Nov 18, 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-53 and 65-71 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-27, 29-33, 35, 37-43, 45, 46, and 65 is/are allowed.
- 6) ☒ Claim(s) 28, 34, 36, 44, 47-53, and 66-71 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 17, 20 6) ☐ Other:

Pursuant to the directives of paper No. 19 (filed 11/18/02), claims 1 and 9 have been amended. Claims 1-53, 65-71 remain pending.

Applicants' arguments filed 11/18/02 have been considered and found persuasive in part. The §103 rejection of claims 1 and 9-12 is withdrawn.

\*

The following is a quotation of the first paragraph of 35 U.S.C. §112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 69-71 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 69 is drawn to a method of treating a mammal that has been stricken with cancer. Claim 70 is drawn to a method of imaging a tumor in a mammal. However, neither claim is enabled. Based on the information provided (pp. 33-34), it appears that the following claim is enabled:

*100. A method of inhibiting the binding of cyanocolablammin to a transcobalamin protein comprising contacting a compound according to claim 1 with a transcobalamin protein for a time and under conditions effective to inhibit the binding of cyanocolablammin to the transcobalamin protein.*

However, this is neither a therapeutic nor diagnostic utility. Perhaps also, there is enablement for a claim that is drawn to a method of *determining the anatomical location of* the compounds in question. Again, however, this is neither a therapeutic nor diagnostic utility. In addition, there is possibly a case to be made that, given what is known in the art about boron and neutron capture therapy, the following claim would be enabled:

*101. A method of inhibiting growth of tumor cells comprising*

*(a) contacting tumor cells with a compound according to claim 1 for a time and under conditions effective to achieve binding between the tumor cells and the compound according to claim 1, and*

*(b) irradiating the tumor cells of step (a) with the compound according to claim 1, for a time and under conditions effective to inhibit growth of said tumor cells.*

However, none of these methods is actually a therapy; in addition, while it should be possible to determine the location of the claimed compounds following administration to a mammal, there is no evidence that any of the claimed compounds will specifically localize at the site of a tumor.

Accordingly, it is suggested that claims 69-71 be cancelled. In addition, if deemed appropriate, claims 100-101 (above) could be added for consideration.

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Claims 28, 34, 36, 44, 47-53, 66-71 are rejected under 35 U.S.C. §112 second paragraph,

as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- Claim 28 recites the term "about" in reference to a range. Applicants have argued that *W.L. Gore & Associates Inc v Garlock, Inc* gives applicants license to use the term "about" in any and all situations. However, the cited case does not refer to the use of the term "about" in reference to a range. It remains the case that the claim is indefinite as to the upper and lower limits of the range.
- In claim 34, the structure of a diaminocyclohexyl metal chelator is presented. There are two points. First, substituent variable "M" is undefined. Second, a hyphen appears to the right of one occurrence of  $R^3$ , but not the other. What is the significance of this hyphen?
- Claim 34 recites that " $R^3$  may be  $C_{1-4}$  alkyl or  $CH_2COO-$ ". However, the phrase "may be" conveys that these are only suggestions for  $R^3$ , and that  $R^3$  can be anything. Is it the case that  $R^3$  can be anything, or is  $R^3$  limited to specific substituents?
- Claim 34 recites that " $R^3$  may be  $C_{1-4}$  alkyl or  $CH_2COO-$ ". In this second formula ( $CH_2COO-$ ), there is a hyphen which is adjacent to the carboxyl group, but not to the methylene group. Is this hyphen intended to indicate bonding? If so, the hyphen should instead be adjacent to the methylene group.
- Claim 36 recites that the molecule comprising B-10 contains "about 1" boron atom. What is meant by "about 1" boron atom? Is "zero" boron atom included?
- Claim 44 recites that claim 1 "further comprises a detectable radionuclide". Is this in addition to the detectable radionuclide already referred to in claim 1? If so, claim 1 should be amended to recite this as a possibility. See also claim 66
- Claim 69 is indefinite as to the process steps of the "administering neutron capture

therapy". What does the medical practitioner do, and what does he (or she) see? Does the neutron capture therapy require any external energy source? Does the neutron capture therapy require administration of a compound, either claimed or not claimed?

- Claim 70 recites "detecting" the presence of the tumor. What steps are involved here? For example, if a tumor-bearing rat were placed inside of a glass cage, would the detection occur automatically? Is instrumentation required? If instrumentation is required, is there a specific type of instrumentation required; is there a specific type of detector on the instrumentation that is required?
- Claim 70 is drawn to a method for imaging a tumor. Claim 70 is not drawn to a method of treating a mammal afflicted with cancer, nor is claim 70 drawn to a two-step process, the first step of which is imaging a tumor, and the second step of which is treating the mammal that is bearing the tumor. Accordingly, claim 71 is indefinite, perhaps even contradictory.

✱

References "AH", "AI" and "AJ" were stricken from the IDS. If these references are to be considered, a complete citation will be required. This includes the journal name, the volume number and the year of publication. Reference "AA" was stricken from the IDS because a copy of the patent was not provided.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 703-308-3213. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached at (703) 308-2923. The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



DAVID LUKTON  
PATENT EXAMINER  
04/01/98